Canadian Agency for Drugs and Technologies in Health

RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

TITLE: Negative Pressure Wound Therapy for Patients with Diabetic Foot Ulcers and Pressure Ulcers: A Review of the Clinical Effectiveness

DATE: 21 June 2012

CONTEXT AND POLICY ISSUES

Diabetic foot ulcer (DFU) is a common diabetic complication.[1] From 2006 to 2008, it was reported that the prevalence for DFU in Medicare beneficiaries was about 8% in the United States.[2] DFU affects patients' quality of life significantly and also has a significant financial impact on healthcare system. A delay in management of DFU will increase morbidity and mortality and results in a higher amputation rate.[3] Management of DFU is still a major therapeutic challenge throughout the world.[4]

Pressure ulcers (PU), also known as decubitus ulcers or bedsores, are caused by uninterrupted pressure on soft tissues overlying a bony prominence which obstructs the blood flow to the superficial tissues. The most commonly affected body parts are the sacrum or the hips, but other sites such as the elbows or knees can be affected.[5] People with reduced mobility and poor skin condition in nursing homes or hospitals are more likely afffected.[5] Approximately 3 million adults in the United States suffer from pressure ulcers. The reported incidence of PU varies from 0.4% to 38.0%.[6-8] The healing rates of the PU varies depending on the severity of PU, comorbidities and clinical management.[6] The estimated costs of treatment for a PU ranges from $37,800 to $70,000. in the United States.[6,7,9]

The management of DFU and PU is important to public health.[1,4,10,11] Negative Pressure Wound Therapy (NPWT), also known as vacuum assisted closure therapy (VAC), topical negative pressure therapy or vacuum compression therapy[1,12,13] appears to be an effective treatment for DFU and PU.[10,14-17] The negative pressure can be delivered continuously or intermittently.[18-20] Most existing clinical evidence is derived from the use of open-cell polyurethane foam at -125 mmHg.[21-24] However, this pressure may cause pain and ischemia and often has to be reduced.[23,24]

Recently, two new NPWT systems (Smith & Nephew PICO[2,25] and KCI V.A.C.Via[26]) have been released. These are less powerful NPWT systems that operate at lower pressures and are disposable after each use. More importantly, these newer machines are comparable in cost to standard wound care.

The aim of this review is to evaluate the comparative clinical effectiveness of these new machines or any other NPWT device at different pressures for the treatment of patients with diabetic foot or pressure ulcers.

RESEARCH QUESTIONS

1. What is the comparative clinical effectiveness of negative pressure wound therapy at -75 mmHg, -80 mmHg, and -125 mmHg for patients with diabetic foot ulcers and pressure ulcers?

2. What is the comparative clinical effectiveness of continuous versus intermittent negative pressure wound therapy at -75 mmHg, -80 mmHg, or -125 mmHg for patients with diabetic foot ulcers and pressure ulcers?

KEY MESSAGE

Due to lack of evidence, the comparative clinical effectiveness of negative pressure wound therapy at different pressures or comparative clinical effectiveness of continuous versus intermittent negative pressure wound therapy for patients with diabetic foot ulcers and pressure ulcers remains to be established.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2012, Issue 5), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and abbreviated lists of major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2007 and May 24, 2012.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications, and evaluated the full-text publications for the final article selection, according to the selection criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with diabetic foot ulcers or pressure ulcers
Intervention	Negative Pressure Wound Therapy
Comparator	Q1: Different pressures of NPWT (e.g., -75 mmHg, -80 mmHg, -125 mmHg) Q2: Continuous versus Intermittent NPWT
Outcomes	Wound healing
Study Designs	Health technology assessments, systematic reviews and meta-analysis, randomized controlled trials (RCTs) and non-randomized studies

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 221 citations. Nine additional citations were identified in the grey literature. Upon screening titles and abstracts, 208 citations were excluded, and 22 potentially relevant articles were retrieved for full-text review. Of the 22 potentially relevant reports,[1,3,6,12,13,21,27-42] no studies met the inclusion criteria. That is, no single study compared different pressures of NPWT (such as -75 mmHg, -80 mmHg, -125 mmHg, or other pressures) or compared continuous versus intermittent NPWT in patients with diabetic foot ulcers or pressure ulcers. The main reason for exclusion was lack of appropriate comparator (n = 15 studies). These studies compared NPWT with standard of care, rather than with another type of NPWT device or the same NPWT device operating at different pressures. The study selection process is outlined in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Appendix 1).

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

No evidence was identified on the comparative clinical effectiveness of negative pressure wound therapy at -75 mmHg, -80 mmHg, and -125 mmHg, or other pressures, for the treatment of diabetic foot ulcers or pressure ulcers. Furthermore, no evidence on comparative clinical effectiveness of continuous versus intermittent negative pressure wound therapy in the management of these patients was identified. No trials were identified comparing different devices for the application of negative pressure wound therapy, including Smith & Nephew PICO or KCI V.A.C.Via devices. Well-designed clinical trials are needed for assessing the comparative clinical effectiveness of different pressures for NPWT for the treatment of diabetic foot ulcer and pressure ulcers.

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APPENDIX 1: Selection of Included Studies